

MAY 10 1999



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George W. Johnston
Hoffmann-La Roche Inc.
Patent Law Department
340 Kingsland St.
Nutley NJ 07110

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,808,605

#19

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,808,605, which claims the human drug product POSICOR® (mibepradil dihydrochloride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,130 days. U.S. Patent No. 4,808,605 has an original expiration date of November 10, 2007, subject to the provisions of 35 U.S.C. § 41(b). Accordingly, extension of the patent for 1,130 days will result in an extended expiration date of December 14, 2010.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,130 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 4, 1998 (63 Fed. Reg. 41582). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1326) + 467 \\ &= 1,130 \text{ days}\end{aligned}$$

Since the regulatory review period began July 25, 1992, after the patent issue date (February 28, 1989), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No. : 4,808,605

Granted : February 28, 1989

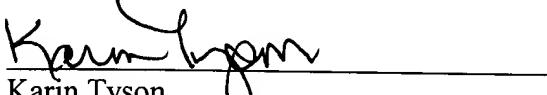
Original Expiration Date	:	November 10, 2007
Applicant	:	Quirico Branca, et al.
Owner of Record	:	Hoffmann-La Roche Inc.
Title	:	Tetrahydronaphthalene Derivatives As Calcium Antagonists
Classification	:	514/394
Product Trade Name	:	POSICOR®
Term Extended	:	1,130 days
Expiration Date of Extension	:	December 14, 2010

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: POSICOR®
FDA Docket No.: 97E-0462